UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,647	07/19/2006	Philip David Monk	102789-1P US	1467

44992 7590 08/13/2009

ASTRAZENECA R&D BOSTON
35 GATEHOUSE DRIVE
WALTHAM, MA 02451-1215

EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,647	MONK ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-21,24,25 and 56-61* is/are pending in the application.

4a) Of the above claim(s) *56-58 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7-21,24 and 25* is/are rejected.

7)☒ Claim(s) *4-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-13-06 6-22-07 and 6-23-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election, amendment and remarks filed June 1, 2009 are acknowledged.

   Claim 1 has been amended.

   Claims 22, 23, 26-55, 59, 60 and 62-91 have been canceled.

   Claims 1, 3, 4-21, 24, 25 and 56-61 are pending.

2. Applicant's election without traverse of Group I and the species of antibody having a substitution of S at position 99 of HCDR3 in the reply filed on June 1, 2009 is acknowledged.

   Thus, claims 1, 3, 4-21, 24 and 25 are under examination wherein the elected species of antibody has a substitution of S at position 99 of HCDR3.

   Moreover, claims 56-58 and 61 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group or species of invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 1, 2009.

3. The text of the claims as filed June 1, 2009 is objected to because it is illegible in many places due to low quality resolution. While this has not prevented the examination of applicant's claims because the illegible terms can be interpreted in context, a higher resolution copy of the claims is needed for future correspondence and any future publication.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

   It does not clearly identify the mailing address of each inventor. Many words of the hand written mailing addresses provided in the Declaration are not entirely legible. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

   Furthermore, the oath has not been signed by inventor Minter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

   > The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, there is insufficient antecedent basis for the limitation "in Table 1" in the claim.

With respect to claims 21, the claim recites "a specific binding member…wherein the whole antibody is IgG4." The claims from which these claims depend recite "a specific binding member…that comprises a whole antibody."

It is unclear what the phrase "the whole antibody is IgG4" means.

On the one hand, this could mean that the rejected claims are limited to a specific binding member which is IgG4, per se, i.e., an IgG4 Fc domain not attached to an IL-13 antigen-binding domain.

On the other hand this could be interpreted to refer to the particular isotype of the claimed specific binding member comprising an IL-13 antigen-binding domain.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 7-21, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of:

An isolated specific binding member for human IL-13, comprising an antibody antigen-binding site which is composed of a human antibody VH domain and a human antibody VL domain and which comprises a set of CDRs HCDR1, HCDR2, HCDR3, LCDR1, LCDR2 and LCDR3, wherein the VH domain comprises HCDR 1, HCDR2 and HCDR3 and the VL domain comprises LCDR1, LCDR2 and LCDR3, wherein the set of CDRs consists of a set of CDRs selected from the group consisting of:

- the BAK278D6 set of CDRs, defined wherein the HCDR1 has the amino acid sequence of SEQ ID NO: 1, the HCDR2 has the amino acid sequence of SEQ ID NO:

2, the HCDR3 has the amino acid sequence of SEQ ID NO: 3, the LCDR1 has the amino acid sequence of SEQ ID NO: 4, the LCDR2 has the amino acid sequence of SEQ ID NO: 5, and the LCDR3 has the amino acid sequence of SEQ ID NO: 6;

- the BAK278D6 set of CDRs, defined wherein the HCDR1 has the amino acid sequence of SEQ ID NO: 1, the HCDR2 has the amino acid sequence of SEQ ID NO: 2, the HCDR3 has the amino acid sequence of SEQ ID NO: 3, the LCDR1 has the amino acid sequence of SEQ ID NO: 4, the LCDR2 has the amino acid sequence of SEQ ID NO: 5, and the LCDR3 has the amino acid sequence of SEQ ID NO: 6, and wherein the BAK278D6 CDR amino acid residues considered together contain overall two amino acid substitutions, wherein said two amino acid substitutions occur at any two residues selected from the following, using the standard numbering of Kabat: 31 in HCDR1; 52, 52A, 53, 54, 56 and 58 in HCDR2; 97 and 99 in HCDR3 and 27 in LCDR1; OR

- the BAK278D6 set of CDRs, defined wherein the HCDR1 has the amino acid sequence of SEQ ID NO: 1, the HCDR2 has the amino acid sequence of SEQ ID NO: 2, the HCDR3 has the amino acid sequence of SEQ ID NO: 3, the LCDR1 has the amino acid sequence of SEQ ID NO: 4, the LCDR2 has the amino acid sequence of SEQ ID NO: 5, and the LCDR3 has the amino acid sequence of SEQ ID NO: 6, wherein the BAK278D6 CDR amino acid residues considered together contain overall up to eight amino acid substitutions, the first two being any two residues selected from the following, using the standard numbering of Kabat: 31 in HCDR1; 97 and 99 in HCDR3 and 27 in LCDR1, the remaining up to six amino acid substitutions being any combination of up to six substitutions at any of up to six residues selected from the following, using the standard numbering of Kabat: 52, 52A, 53, 54, 56 and 58 in HCDR2;

- the BAK278D6 set of CDRs, defined wherein the HCDR1 has the amino acid sequence of SEQ ID NO: 1, the HCDR2 has the amino acid sequence of SEQ ID NO: 2, the HCDR3 has the amino acid sequence of SEQ ID NO: 3, the LCDR1 has the amino acid sequence of SEQ ID NO: 4, the LCDR2 has the amino acid sequence of SEQ ID NO: 5, and the LCDR3 has the amino acid sequence of SEQ ID NO: 6, and wherein the BAK278D6 CDR amino acid residues considered together contain overall one amino acid substitution wherein said one amino acid substitutions occurs at one residue selected from the following using the standard numbering of Kabat: 31, 32 and 34 in HCDR1; 52, 52A, 53, 54, 56, 58, 60, 61, 62, 64 and 65 in HCDR2; 96, 87, 97, 98, 99 and 101 in HCDR3; 26, 27, 28, 30, 31 in LCDR1; 56 in LCDR2 and 95A and 97 in LCDR3;

- compositions comprising the above recited embodiments or an isolated specific binding member for human IL-13 wherein said isolated specific binding member comprises an antibody Vh domain and an antibody VL domain, wherein the Vh

domain is a Vh domain according to the above recited embodiments and/or wherein the VL domain is a VL domain according to the above recited embodiments.

However, applicant is not in possession of

the breadth of antibodies encompassed by claim 1 which includes antibodies having two substitutions within the CDRs using the standard number of Kabat including at a variety of CDR residues where the specification has exemplified either a non-representative number of possible substitutions and/or type of substitutions, i.e., the 13 positions where one substitution has been exemplified and the 3 positions where two substitutions have been exemplified as well as the one position where three substitutions of a similar chemical nature (hydrophobic) have been exemplified; or for the breadth of antibodies encompassed by claim 1 which also includes one or two substitutions at each of the residues recited in each and every CDR for a total of 11 amino acid residues with any amino acid substitution in each;

OR for the compositions of claims 24 and 25 which includes a composition comprising the antibody Vh domain or antibody VL domain according to claim 1 where said antibody Vh domain or antibody VL domain according to claim 1 can be present in the absence of a complimentary VL or Vh domain.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Vas-Cath, Inc., v. Mahurkar, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116.

The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, such as its ability to bind IL-13, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. In re Bell, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). In re Deuel, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995).

In the instant case, the specification discloses and exemplifies several methods of making anti-IL-13 antibody variants.

For example, in one method HCDR3 or (HCDR1 and HCDR2) of a particular anti-IL-13 antibody, such as the BAK502G9 antibody are subjected to random mutagenesis and antibodies that bind IL-13 are selected (see Example 3 and 5, respectively). Some of the variants produced by said mutagenesis and selection strategies are shown in the Table 1 rows marked "PD".

In another method, a starting anti-IL-13 antibody such as the BAK278D6 anti-IL-13 antibody is subjected to mutagenesis and those variants retaining IL-13 binding affinity are selected to produce first variants, said first variants are re-mutagenized to produce second variants and then second variants having progressively better IL-13 binding affinity are retained and so on (see Example 1).

The result of said mutagenesis and progressively higher affinity selection strategy is also shown in Table 1 in the rows marked "RD".

However, neither the teachings of the instant specification nor the knowledge in the art are sufficient to demonstrate possession of the genus of antibodies encompassed by claim 1 and dependent claims thereof.

For example, while the instant specification exemplifies the selection and characterization of a number of variants of an antibody antigen-binding site which is composed of a human antibody VH domain and a human antibody VL domain and which comprises the BAK278D6 CDRs defined wherein the HCDR1 has the amino acid sequence of SEQ ID NO: 1, the HCDR2 has the amino acid sequence of SEQ ID NO: 2, the HCDR3 has the amino acid sequence of SEQ ID NO: 3, the LCDR1 has the amino acid sequence of SEQ ID NO: 4, the LCDR2 has the amino acid sequence of SEQ ID NO: 5, and the LCDR3 has the amino acid sequence of SEQ ID NO: 6, this disclosure is not adequate for the skilled artisan to extrapolate to the breadth of antibodies encompassed by the instant claim which includes one or two substitutions at each of the residues recited in each and every CDR (31, 32 and 34 in HCDR1; 52, 52A, 53, 54, 56, 58, 60, 61, 62, 64 and 65 in HCDR2; 96, 87, 97, 98, 99 and 101 in HCDR3; 26, 27, 28, 30, 31 in LCDR1; 56 in LCDR2 and 95A and 97 in LCDR3) for a total of 11 amino acid residues with any amino acid substitution in each.

One reason the skilled artisan cannot predictably extrapolate from the disclosure of the instant specification to the breadth of antibodies encompassed by claim 1 and dependent claims thereof is as follows:

The variant antibodies compiled in Table 1 of the instant specification were isolated by a variety of mutagenesis and selection procedures; however, the instant specification does not seem to indicate the degree to which the mutants presented represent the diversity or redundancy of the mutant libraries, i.e., are these all the mutants that could ever be obtained from the library, or some fraction thereof, and just how representative was the library of the spectrum of possible mutants? In the absence of this knowledge the skilled artisan can only guess as to the flexibility in any particular residue that has not been characterized in a representative way by the instant specification, such as position 56 in LCR2.

Moreover, there is a level of unpredictability in the art associated with making single versus multiple changes to any given CDR. For example, Brown et al. (J Immunol. 1996 May 1;156(9):3285-91), describes how the Vh CDR2 in a particular antibody was generally tolerant of single amino acid changes, however the antibody lost binding upon the

introduction of two amino changes in the same region. (see, in particular Tables I and II and column bridging paragraph on page 3290).

While direct comparisons between the teachings of Brown and the disclosure of the instant specification are not apt given the apparent flexibility of certain residues with the HCDR2 of the instant claims versus the particular teachings of Brown concerning the HCDR2 of the anti-phosphocholine antibody T15, Brown still supports the general principal that multiple substitutions in CDRs have a degree of unpredictability that extends beyond that which would be expected by the skilled artisan based on a consideration of the simple additive effects of single amino acid substitutions in any given CDR.

Furthermore, the guidance and direction provided by the instant specification with respect to certain CDR residues recited in the claims is insufficient in that the specification has exemplified either a non-representative number of possible substitutions and/or type of substitutions, i.e., the 13 positions where one substitution has been exemplified and the 3 positions where two substitutions have been exemplified as well as the one position where three substitutions of a similar chemical nature (hydrophobic) have been exemplified. Thus, the skilled artisan would have little idea as to the degree to which these residues can be altered, i.e., conservatively or radically, while maintaining sufficient IL-13 binding.

To illustrate this point, consider Vajdos et al. (J Mol Biol. 2002 Jul 5;320(2):415-28, cited on an IDS) which teaches "[t]he specificity and affinity of an antibody for its cognate antigen is determined by the sequence and structure of the variable fragment (Fv): a heterodimer consisting of the N-terminal domains of the heavy and light chains. Even within the Fv, ***antigen binding is primarily mediated by the complementarity determining regions (CDRs), six hypervariable loops (three each in the heavy and light chains) which together present a large contiguous surface for potential antigen binding.*** Aside from the CDRs, the Fv also contains more highly conserved framework segments which connect the CDRs and are mainly involved in supporting the CDR loop conformations, although in some cases, framework residues also contact antigen. As an important step to understanding how a particular antibody functions, it would be very useful to assess the contributions of each CDR side-chain to antigen binding, and in so doing, to produce a functional map of the antigen-binding site." (see, page 416, column bridging paragraph, emphasis added).

Vajdos goes on to teach that "[b]y analyzing panels of point mutants, a detailed map of the binding energetics can be obtained, but the process can be ***very laborious*** because ***individual mutant proteins must be made and analyzed separately.*** In particular, ***a comprehensive analysis*** of an antigen binding site would ideally ***encompass all CDR residues***, and this would require the analysis of dozens or even hundreds of point mutants." (see page 416, right column, first paragraph, emphasis added). Vajdos solution to this dilemma was to make use of a recently developed shotgun scanning mutagenesis which "uses phage displayed libraries of protein mutants constructed using degenerate codons with restricted diversity." While this "recently developed shotgun scanning mutagenesis" is an improvement over previous strategies as taught by Vajdos, it nonetheless requires extensive planning and analysis and

involves the synthesis of 18 sets of degenerate oligonucleotides for the construction of the 4 phage libraries required to comprehensively scan the heterodimeric chains of the antibody (see, in particular, page 416, right column, 2nd paragraph and pages 425-427, Materials and Methods.)

Furthermore, even after performing this comprehensive scanning mutagenesis of all CDR residues from the particular anti-ErB2 antibody under study, Vajdos would still not have been able to say which CDR residues are actually involved in antigen binding, and which are involved in stabilizing the secondary and tertiary structure of the CDRs within the context of the heavy and light chains as a whole, without the structure of the unbound antigen-binding site of the antibody to aid in their analysis (see, in particular, Discussion, pages 422-425).

Rather, Vajdos needed to perform not only a comprehensive shotgun scanning mutagenesis of all CDR residues of the antibody under study but also needed a structure of the unbound antigen-binding site in hand to gain a sufficient understanding of the contribution of each CDR to antigen-binding that would be required to adequately predict which CDR residues can be mutated, and to what extent, or in what context of additional compensatory mutations in other regions of the antibody. Moreover, given an amino acid substitution that ablated binding, without the crystal structure in hand, still further experimentation would have been required to determine the flexibility in this particular residue, i.e., it's general tolerance or intolerance to change.

Moreover, there are additional issues with claims 24 and 25. These claims recite "a composition comprising a specific binding member, antibody Vh domain or antibody VL according to claim 1…," which, given its broadest reasonable interpretation consistent with the instant specification and with the knowledge in the art encompasses not only specific binding members having both a Vh and VL domain as recited in claim 1 but also compositions comprising "antibody Vh domain or antibody VL according to claim 1" not paired with a complimentary VL or Vh domain, i.e., even when the recited Vh or VL domain is not part of a conventional Vh/VL containing antibody (see instant specification paragraph bridging pages 19-20 and page 31, 2nd paragraph).

While Vh and Vl single domain antibodies were known in the art as of applicant's date of invention (see e.g., Van den Beucken et al., J Mol Biol. 2001 Jul 13;310(3):591-601), the instant specification provides no guidance or teaching that the Vh or VL domains encompassed by the instant claims have the necessary structure to bind IL-13 in the absence of a complimentary Vl or VH. Furthermore, while the skilled artisan knows that antibodies can be made to bind to ligands that they would not otherwise bind under a variety of extremely non-physiologic antibody and antigen concentrations, total protein, salt and/or detergent conditions in vitro, the instant specification provides no direction or guidance as to the particular in vitro conditions that would allow isolated Vh or VL domains recited in claims 24 and 25 to bind IL-13.

Conclusion

Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("definition by function … does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is").

Without this guidance or direction the skilled artisan would not consider applicant to be in possession of the claimed genus of antibodies because the skilled artisan recognizes that even seemingly minor changes made without guidance or direction as to the relationship between the particular amino acid sequence of the instantly claimed antibody and its ability to bind antigen, can dramatically affect antigen-antibody binding.

Applicant has not described the claimed invention sufficiently to show they had possession of the claimed genus of specific binding members for IL-13 and compositions thereof.

Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004).

Moreover, according to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, MPEP 2163 II.A.3a.ii.

Applicant is directed to the Revised Guidelines for the Examination of Patent Applications Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001).

9. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachary Skelding/
Examiner, Art Unit 1644